TOPICAL ANALGESIC- dermaline arnica menthol gel gel
Dermaline USA Corp

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Dermaline Arnica Gel

Active Ingredient(s)

Menthol 1%. Purpose: Topical Analgesic

Purpose

Topical Analgesic, Gel

Use

For temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritation.

Warnings

For external use only. Flammable. Keep away from fire or flames.

Avoid Contact with eyes. Do not bandage tightly.

Do not apply over large areas of the body.

Do not use

- on children under 16 years of age except on the advice of a physician.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Incase accidental ingestion, get medical help or contact a Poison Control Center right away.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 16 years of age and older: Wash the affected area with mild soap and warm

water and rinse thoroughly. Apply to affected area not more than 3 to 4 times daily.

Do not bandage tightly or apply to wounds or damaged skin.

Children under 16 yeats of age: consult a doctor.

Other information

- Store between 15-30C (59-86F)
- Do not expose to excessive heat.

Inactive ingredients

Arnica Extract, Camphor, Carbomer, Deionized Water, DMDM Hydatoin, Ethyl Alcohol, Eucalyptus Oil, Isopropyl Alcohol, Nonoxynol-9, polysorbate 20, propyleneglycol, Tea Tree Oil, Trirthanolamine.

Package Label - Principal Display Panel

1.95″ x 8″

141 g

TOPICAL ANALGESIC

dermaline arnica menthol gel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82165-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
AMMONIUM NONOXYNOL-9 SULFATE (UNII: 8Y8LQ8CRCC)	
2-PHENYLPROPANAL PROPYLENE GLYCOL ACETAL (UNII: 1ZRR9A405A)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
TEA TREE OIL (UNII: VIF565UC2G)	
CUPRIC TRIETHANOLAMINE (UNII: 6NU949U74E)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ARNICA MONTANA (UNII: O80TY208ZW)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82165-104-05	141 g in 1 JAR; Type 0: Not a Combination Product	05/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/10/2021	

Labeler - Dermaline USA Corp (016069241)

Revised: 2/2023 Dermaline USA Corp